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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,216	01/20/2004	Stephen F. Kingsmore	071949-5914	6434

7590 10/06/2006

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,216	KINGSMORE ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-95* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-95* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-23 and 59-64 are drawn to a method of diagnosing sepsis in a human subject, comprising comparing concentration of at least one analyte in a test sample from said human subject to concentration of said at least one analyte in a reference range that was determined for one or more control samples obtained from one or more human subjects not suffering from sepsis, wherein the at least one analyte is recited, classified in class 436, subclass 16.

II. Claims 24-28 are drawn to a method of diagnosing sepsis in a human subject, comprising comparing concentration of at least two analyte in a test sample from said human subject to concentration of said at least two analyte in a reference range that was determined for one or more control samples obtained from one or more human subjects not suffering from sepsis, wherein the first and second analytes are recited, classified in class 435, subclass 3.

III. Claims 29-49 are drawn to a method of diagnosing sepsis in a human subject, comprising comparing concentration of at least one analyte in a test sample from said human subject to concentration of said at least one analyte in a reference range that was determined for one or more control samples obtained from one or more human subjects not suffering from

sepsis, wherein the at least one analyte is recited, classified in class 435, subclass 70.21.

IV. Claims 50-58 and 65-73 are drawn to a method of diagnosing sepsis in a human subject, comprising comparing in a test sample from said human subject of at least one analyte in a test sample from said human subject to concentration of said at least one analyte selected from a first and second group to concentration of said analytes in a reference range that was determined for one or more control samples obtained from one or more human subjects not suffering from sepsis, classified in class 436, subclass 501.

V. Claims 74-77 are drawn to a method of diagnosis of deterioration or risk of progression to severe sepsis in a human subject suspected of having or having sepsis, the method comprising determining the concentration of one or more analytes in a first sample obtained from said subject, wherein the one or more analyte is recited, classified in class 435, subclass 7.1.

VI. Claims 78-87 are drawn to a method of diagnosing sepsis in an acutely ill human subject at risk of developing sepsis, classified in class 435, subclass 513.

VII. Claims 88-91 are drawn to a method of diagnosis of improvement in a human subject suspected of having or having sepsis, classified in class 435, subclass 4.

VIII. Claims 92-95 are drawn to a method of diagnosis of deterioration or risk of progression to severe sepsis comprising determining the concentration of one or more analytes in a sample, comparing the concentration to determine the indication of deterioration or risk of progression to severe sepsis, classified in class 436, subclass 15.

2. The inventions are distinct, each from the other because of the following reasons:

(i) Inventions I and any of Groups II- IIIV are related as distinct methods because they are different methods with different method steps; reagents; functions and each result in different final outcomes. First, the instant specification does not disclose that these methods would be used together, rather the specification beginning at page 4 states that the methods are separate and distinct embodiments. The methods are all unrelated as they comprise distinct steps and utilize different products which demonstrate that each method has a different mode of operation. Each invention performs its function using a structurally and functionally divergent material. For instance, the methods use II and IV recite the use of different analytes in their second groups. Group VIII is separate and distinct, from the other groups since only group VIII comprises the use control samples from subjects who have sepsis. Furthermore, only group I is drawn to a method of preparing a monoclonal antibody. This method is separate and distinct from any other method. Therefore, each method is divergent with respect to the analytes used and their associated comparison and determination steps. For these reasons the inventions I-VIII are patentably distinct.

Furthermore, searching the inventions of groups I-V III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A method of diagnosis of deterioration or risk of progression to severe sepsis comprising determining the concentration of one or more analytes in a sample, comparing the concentration to determine the indication of deterioration or risk of progression to severe sepsis, using control samples from subjects who have sepsis requires a different search, than the other methods. Moreover, a search drawn to a method of diagnosing sepsis in a human subject, comprising comparing concentration of at least one analyte in a test sample from said human subject to concentration of said at least one analyte in a reference range that was determined for one or more control samples obtained from one or more human subjects not suffering from sepsis, wherein the at least one analyte as recited may not encompass a search for the other methods which comprise the use of additional analytes, different controls, reference ranges and different comparison and determination steps. Furthermore, the method of group I may be known even if the method of group VII is novel. In addition, the technical literature search for the method of group I and the method of groups II-VIII are not coextensive, since, for instance, the method group I may be characterized in the technical literature prior to discovery of the method of group III.

3. The inventions of Groups I-VIII have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any combination of the inventions of Groups I-VIII together.

4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, A. Mark Navarro can be reached on 571-272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
September 28, 2006